



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/990,499 | 11/21/2001 | Raman K. Bakshi | 20385YDA | 4343 |

210 7590 08/09/2002

MERCK AND CO INC
P O BOX 2000
RAHWAY, NJ 070650907

EXAMINER

SEAMAN, D MARGARET M

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1625

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,499

Applicant(s)

BAKSHI ET AL.

Examiner

D. Margaret Seaman

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application was filed 21 November 2001 and is a DIV of 09/585,111 (filed 1 June 2000) and claims benefit of 60/137,477 (4 June 1999) and claims benefit of 60/169,209 (2 December 1999). Claims 1-38 have been canceled and new claims 39-75 have been entered, per paper #4, dated 12 June 2002. Claims 39-75 are before the Examiner.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-38, now canceled and replaced with claims 39-75, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated in paper #2, dated 11 March 2002, is upheld. The specification does not enable the ordinary artisan to choose a compound that is other than patented in the parent case, namely a substituted isoquinoline. The entire specification is drawn to substituted isoquinoline compounds of formula (I) that are MC-4R agonists. There is no teaching in the specification that would lead one of ordinary skill in the art to compounds other

than formula (I). Without a teaching of what other compounds to pursue, the specification is seen to be lacking in enablement for the instant claims. Without guidance, the instant specification is an invitation to test any and all known and unknown compounds for their ability to bind selectively and be agonists of MC-4R.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) *The breadth of the claims:* The claims are drawn to treatment of sexual dysfunction in a male subject with any compound that is a MC-4R agonist.

2) *The nature of the invention:* The invention is drawn to treatment of male erectile dysfunction by using a MC-4R agonist wherein the binding of the compound to MC-4R is characterized by an IC₅₀ of less than 30 nanomolar and the binding of the compound to the human MC-1R is characterized by an IC₅₀ greater than 30 nM..

3) *The state of the prior art:* The prior art discusses treating male erectile dysfunction by using certain families of compounds that are MC-4R, MC-3R, MC-2R, MC-1R, and

MC-5R agonists. However, the art is silent about what other compounds or families of compounds might be MC-4R agonists.

5) *The level of predictability in the art:* It has not been shown that there is any level of predictability in the art.

6) *The amount of direction provided by the inventor:* The inventor has provided direction only for the compounds of formula (I) treating male erectile dysfunction. However, there is no direction provided by the inventor to treat male erectile dysfunctions with any compound that is other than a compound of formula (I).

7) *The existence of working examples:* The only working examples of MC-4R agonists are of formula (I).

8) *The quantity of experimentation needed to make or use the invention based on the content of the disclosure:* The experimentation needed to make or use the instant invention is undue. There is no guidance of what kind of compound to choose other than of formula (I) to be a MC-4R agonist. The ordinary artisan would be forced to pick compounds at random from all known and unknown compounds to test them randomly to see if they are MC-4R agonists having the other parameters that are disclosed in the claims. This is very extensive and undue experimentation.

Taking these into consideration, it is not seen where the instant specification enables the ordinary artisan to make and/or use the instant invention. The rejections of claims 39-75 is upheld.

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

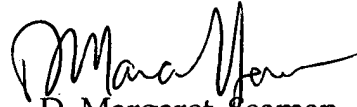
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Art Unit: 1625

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read "D. Margaret Seaman".

D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms
August 6, 2002